

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

| | | |
|---|---|---|
| Applicant's or agent's file reference PS72 PCT | FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT IPEA 416) | |
| International application No PCT US00 16895 | International filing date (day month year) 19 June 2000 (19 06 2000) | Priority date (day month year) 17 June 1999 (17 06 1999) |
| International Patent Classification (IPC) or national classification and IPC IPC(7): A01N 1/02 and US Cl.: 435 1.1, 1.2 | | |
| Applicant THE REGENTS OF UNIVERSITY OF CALIFORNIA | | |
| <p>1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of <u>4</u> sheets, including this cover sheet.</p> <p><input type="checkbox"/> This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).</p> <p>These annexes consist of a total of <u>0</u> sheets.</p> <p>3. This report contains indications relating to the following items:</p> <p>I <input checked="" type="checkbox"/> Basis of the report</p> <p>II <input type="checkbox"/> Priority</p> <p>III <input type="checkbox"/> Non-establishment of report with regard to novelty, inventive step and industrial applicability</p> <p>IV <input type="checkbox"/> Lack of unity of invention</p> <p>V <input checked="" type="checkbox"/> Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p>VI <input type="checkbox"/> Certain documents cited</p> <p>VII <input type="checkbox"/> Certain defects in the international application</p> <p>VIII <input type="checkbox"/> Certain observations on the international application</p> | | |
| Date of submission of the demand 10 January 2001 (10.01 2001) | Date of completion of this report 11 February 2002 (11.02 2002) | |
| Name and mailing address of the IPEA US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20530 Facsimile No. (703) 305-3230 | Authorized officer Sandra Sadler Telephone No. (703) 308-0119 | |

Form PCT IPEA 409 (cover sheet) July 1998)

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT US00 168

1. Basis of the report

1. With regard to the **elements** of the international application *

- ☐ the international application as originally filed.
- ☐ the description:
pages 1-57 as originally filed
pages NONE, filed with the demand
pages NONE, filed with the letter of _____
- ☐ the claims:
pages 58, as originally filed
pages NONE, as amended (together with any statement) under Article 19
pages NONE, filed with the demand
pages NONE, filed with the letter of _____
- ☒ the drawings
pages 1-5, as originally filed
pages NONE, filed with the demand
pages NONE, filed with the letter of _____
- ☐ the sequence listing part of the description:
pages NONE, as originally filed
pages NONE, filed with the demand
pages NONE, filed with the letter of _____

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language _____ which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in printed form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☒ The amendments have resulted in the cancellation of

- ☒ the description, pages none
- ☒ the claims, Nos. none
- ☒ the drawings, sheets fig none

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)) **

* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17)

** Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report

V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability: citations and explanations supporting such statement**1. STATEMENT**

| | | |
|-------------------------------|--------------------|-----|
| Novelty (N) | Claims <u>1</u> | YES |
| | Claims <u>2,3</u> | NO |
| Inventive Step (IS) | Claims <u>NONE</u> | YES |
| | Claims <u>1-3</u> | NO |
| Industrial Applicability (IA) | Claims <u>1-3</u> | YES |
| | Claims <u>NONE</u> | NO |

2. CITATIONS AND EXPLANATIONS

Claim 2 lacks novelty under PCT Article 33(2) as being anticipated by WINSLOW (US 5,814,601).

The claim is drawn to a solution for organ preservation comprising PEG coated bovine hemoglobin.

US 5,814,601 discloses hemoglobin from bovine origins coated with PEG (col. 11, lines 18 and 28).

Claims 2 and 3 lack novelty under PCT Article 33(2) as being anticipated by Nakajima et al.

Claim 2 has been discussed above and claim 3 is drawn to a composition further comprising and oxygen, nutritional and electrolyte environment.

Nakajima et al. disclose a composition comprising hemoglobin and polyoxyethylene in a solution with glucose and electrolytes (page 277, Materials and Methods and Table 1) which creates an oxygen, nutritional and electrolyte environment.

Claim 1 lacks an inventive step under PCT Article 33(3) as being obvious over SEGEL ((US 5,374,624) in view of STRASBERG et al. (US 5,200,398).

The claim is drawn to a composition for organ preservation comprising PEG-Hb, human albumin, dextrose, sodium heparin, lidocaine HCL, MgSO₄, KCl, CaCl₂, THAM, NaCl, NaHCO₃ and Na₃PO₄.

US 5,374,624 discloses a composition comprising fluorochemicals, albumin, dextrose, sodium heparin, lidocaine, MgCl₂, KCl, CaCl₂, NaCl, NaHCO₃ and KH₂PO₄. This composition lacks the inclusion of THAM and SO₄ ion. All other ions of the claimed solution are present in the solution of the reference.

Many crystalloid solutions used for organ preservation such as Eurocollins' solution have Mg₂SO₄ as the magnesium salt instead of MgCl₂. As no criticality has been demonstrated, the use of Mg₂SO₄ as a substitute for MgCl₂ is considered to be the substitution of equivalents and both have been used in preservative solutions as shown in US 5,200,398 (Table 1). With regard to the inclusion of THAM, this is a conventional biological buffer and its addition to a solution in order to stabilize pH cannot be considered to be inventive.

----- NEW CITATIONS -----

US 5,200,398 A (STRASBERG et al.) 06 April 1993, see Table 1.

Supplemental Box

(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of Section I. Basis of the report, Item 5

The amendment of the description claim filed 25 June 2001 is objected to under PCT Article 34(2)(b) because it adds matter into the application that goes beyond the disclosure as originally filed. The added matter which is new is as follows. On 25 June 2001, amendments were submitted to claims disclosure figures under Article 19. However, Article 19 amendments are only made to the claims during the search phase. Thus, the amendments to the description and figures under Article 19 were improper. Also, as the demand was filed 10 January 2001 and the written opinion (408) was mailed 18 May 2001, the application was not in the search phase. Thus, the amendments to the claims under Article 19 was also improper and no amendments under Article 19 have been entered. Further, on 25 June 2001, an amendment to the description and figures was submitted under Article 34. However, it has not been entered because of new matter. For example, in the amended abstract, the perfusion solution comprises Na_2HPO_4 NaH_2PO_4 , while in the original abstract, the perfusion solution comprises Na_3PO_4 . Another example is the amended abstract states that the invention comprises polyethylene CONJUGATED hemoglobin, while the original abstract states that the invention comprises polyethylene glycol COATED BOVINE hemoglobin. This is a change in both the scope of the invention and the substance of the statement of the invention as a conjugated chemical composition differs in structure from one which is a coated composition as coating does not require conjugation. Extensive amendments to the figures description under Article 34 have not been entered as they introduce new matter by changing the scope and substance of the disclosure.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/US00/16895**V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement****1. STATEMENT**

| | | |
|-------------------------------|--------------------|-----|
| Novelty (N) | Claims <u>1</u> | YES |
| | Claims <u>2,3</u> | NO |
| Inventive Step (IS) | Claims <u>NONE</u> | YES |
| | Claims <u>1-3</u> | NO |
| Industrial Applicability (IA) | Claims <u>1-3</u> | YES |
| | Claims <u>NONE</u> | NO |

2. CITATIONS AND EXPLANATIONS

Claim 2 lacks novelty under PCT Article 33(2) as being anticipated by WINSLOW (US 5,814,601).

The claim is drawn to a solution for organ preservation comprising PEG coated bovine hemoglobin.

US 5,814,601 discloses hemoglobin from bovine origins coated with PEG (col. 11, lines 18 and 28).

Claims 2 and 3 lack novelty under PCT Article 33(2) as being anticipated by Nakajima et al.

Claim 2 has been discussed above and claim 3 is drawn to a composition further comprising and oxygen, nutritional and electrolyte environment.

Nakajima et al. disclose a composition comprising hemoglobin and polyoxyethylene in a solution with glucose and electrolytes (page 277, Materials and Methods and Table 1) which creates an oxygen, nutritional and electrolyte environment.

Claim 1 lacks an inventive step under PCT Article 33(3) as being obvious over SEGEL ((US 5,374,624) in view of STRASBERG et al. (US 5,200,398).

The claim is drawn to a composition for organ preservation comprising PEG-Hb, human albumin, dextrose, sodium heparin, lidocaine HCL, MgSO₄, KCl, CaCl₂, THAM, NaCl, NaHCO₃ and Na₃PO₄.

US 5,374,624 discloses a composition comprising fluorochemicals, albumin, dextrose, sodium heparin, lidocaine, MgCl₂, KCl, CaCl₂, NaCl, NaHCO₃ and KH₂PO₄. This composition lacks the inclusion of THAM and SO₄ ion. All other ions of the claimed solution are present in the solution of the reference.

Many crystalloid solutions used for organ preservation such as Eurocollins' solution have Mg₂SO₄ as the magnesium salt instead of MgCl₂. As no criticality has been demonstrated, the use of Mg₂SO₄ as a substitute for MgCl₂ is considered to be the substitution of equivalents and both have been used in preservative solutions as shown in US 5,200,398 (Table 1). With regard to the inclusion of THAM, this is a conventional biological buffer and its addition to a solution in order to stabilize pH cannot be considered to be inventive.

----- NEW CITATIONS -----

US 5,200,398 A (STRASBERG et al.) 06 April 1993, see Table 1.

INTERNATIONAL PRELIMINARY EXAMINATION REPORTInternational application No.
PCT/US00/16895**Supplemental Box**

(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of Section I. Basis of the report, Item 5

The amendment of the description/claim filed 25 June 2001 is objected to under PCT Article 34(2)(b) because it adds matter into the application that goes beyond the disclosure as originally filed. The added matter which is new is as follows: On 25 June 2001, amendments were submitted to claims/disclosure/figures under Article 19. However, Article 19 amendments are only made to the claims during the search phase. Thus, the amendments to the description and figures under Article 19 were improper. Also, as the demand was filed 10 January 2001 and the written opinion (408) was mailed 18 May 2001, the application was not in the search phase. Thus, the amendments to the claims under Article 19 was also improper and no amendments under Article 19 have been entered. Further, on 25 June 2001, an amendment to the description and figures was submitted under Article 34. However, it has not been entered because of new matter. For example, in the amended abstract, the perfusion solution comprises $\text{Na}_2\text{HPO}_4/\text{NaH}_2\text{PO}_4$, while in the original abstract, the perfusion solution comprises Na_3PO_4 . Another example is the amended abstract states that the invention comprises polyethylene CONJUGATED hemoglobin, while the original abstract states that the invention comprises polyethylene glycol COATED BOVINE hemoglobin. This is a change in both the scope of the invention and the substance of the statement of the invention as a conjugated chemical composition differs in structure from one which is a coated composition as coating does not require conjugation. Extensive amendments to the figures/description under Article 34 have not been entered as they introduce new matter by changing the scope and substance of the disclosure.

TENT COOPERATION TREATY

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To
DANIEL L. DAWES
MYERS, DAWES & ANDRAS LLP
650 TOWN CENTER DRIVE
SUITE 650
COSTA MESA, CA 92626

PCT

NOTIFICATION OF TRANSMITTAL OF INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Rule 71.1)

Date of Mailing
(day month year)

06 MAR 2002

Applicant's or agent's file reference

PS-2 PCT

IMPORTANT NOTIFICATION

International application No.

PCT US00 16895

International filing date (day month year)

19 June 2000 (19.06.2000)

Priority date (day month year)

17 June 1999 (17.06.1999)

Applicant

THE REGENTS OF UNIVERSITY OF CALIFORNIA

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary examination report and its annexes, if any, established on the international application.
2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.
3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.
4. **REMINDER**

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices)(Article 39(1))(see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

Name and mailing address of the IPEA US

Commissioner of Patents and Trademarks
Box PCT
Washington, D.C. 20531

Facsimile No. (703)305-3230

Form PCT IPEA 416 (July 1992)

Authorized officer

Sandra Stueker

Telephone No. (703) 308-019

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US00/16895

A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) : A01N 1/02

US CL : 435/1.1, 1.2

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 435/1.1, 1.2

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

Ca on line, USPATFULL, Medline, Biosis

C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category* | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|---------------|--|-----------------------|
| X --- Y | US 5,814,601 A (WINSLOW et al.) 29 September 1998, col. 11 and 12. | 2 --- 1,3 |
| Y | US 5,374,624 A (SEGEL) 20 December 1994, Table 1. | 1-3 |
| X | NAKAJIMA et al. Forty-eight hour liver preservation using an artificial blood substitute. Asaio Transactions. Jul-Sep 1988, Vol. 34, No. 3, pages 277-279, especially Table 1. | 2,3 |

☐

Further documents are listed in the continuation of Box C.

☐

See patent family annex.

| | |
|---|--|
| * Special categories of cited documents | *T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention |
| *A* document defining the general state of the art which is not considered to be of particular relevance | *X* document of particular relevance, the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone |
| *E* earlier document published on or after the international filing date | *Y* document of particular relevance, the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art |
| *L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) | *G* document member of the same patent family |
| *O* document referring to an oral disclosure, use, exhibition or other means | |
| *P* document published prior to the international filing date but later than the priority date claimed | |

Date of the actual completion of the international search

23 AUGUST 2000

Date of mailing of the international search report

20 SEP 2000

Name and mailing address of the ISA/US
Commissioner of Patents and Trademarks
Box PCT
Washington, D.C. 20231

Facsimile No. (703) 305-3230

Authorized officer

SANDRA SAUCIER

Telephone No. (703) 308-0196

PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY

To: DANIEL L. DAWES
MYERS, DAWES & ANDRAS LLP
650 TOWN CENTER DRIVE, SUITE 650
COSTA MESA, CA 92626

PCT

NOTIFICATION OF TRANSMITTAL OF THE INTERNATIONAL SEARCH REPORT OR THE DECLARATION

(PCT Rule 44.1)

| | |
|--|---|
| Date of Mailing (day/month/year) | 20 SEP 2000 |
| Applicant's or agent's file reference NONE | FOR FURTHER ACTION See paragraphs 1 and 4 below |
| International application No. PCT/US00/16895 | International filing date (day/month/year) 19 JUNE 2000 |
| Applicant REGENTS OF THE UNIVERSITY OF CALIFORNIA | |

1. ☒ The applicant is hereby notified that the international search report has been established and is transmitted herewith.

Filing of amendments and statement under Article 19:

The applicant is entitled, if he so wishes, to amend the claims of the international application (see Rule 46):

When? The time limit for filing such amendments is normally 2 months from the date of transmittal of the international search report; however, for more details, see the notes on the accompanying sheet.

Where? Directly to the International Bureau of WIPO
34, chemin des Colombettes
1211 Geneva 20, Switzerland
Facsimile No.: (41-22) 740.14.35

For more detailed instructions, see the notes on the accompanying sheet.

2. ☐ The applicant is hereby notified that no international search report will be established and that the declaration under Article 17(2)(a) to that effect is transmitted herewith.

3. ☐ **With regard to the protest** against payment of (an) additional fee(s) under Rule 40.2, the applicant is notified that:

☐ the protest together with the decision thereon has been transmitted to the International Bureau together with the applicant's request to forward the texts of both the protest and the decision thereon to the designated Offices.

☐ no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made.

4. **Further action(s):** The applicant is reminded of the following:

Shortly after **18 months** from the priority date, the international application will be published by the International Bureau. If the applicant wishes to avoid or postpone publication, a notice of withdrawal of the international application, or of the priority claim, must reach the International Bureau as provided in rules 90 *bis* 1 and 90 *bis* 3, respectively, before the completion of the technical preparations for international publication.

Within **19 months** from the priority date, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase until 30 months from the priority date (in some Offices even later).

Within **20 months** from the priority date, the applicant must perform the prescribed acts for entry into the national phase before all designated Offices which have not been elected in the demand or in a later election within 19 months from the priority date or could not be elected because they are not bound by Chapter II.

Name and mailing address of the ISA/US
Commissioner of Patents and Trademarks
Box PCT
Washington, D.C. 20231

Facsimile No. (703) 305-3230

Authorized officer

SANDRA SAUCIER

Telephone No. (703) 308-0196

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

| | | |
|---|---|---|
| Applicant's or agent's file reference NONE | <div style="display: flex; justify-content: space-between;"> <div style="text-align: center;">FOR FURTHER ACTION</div> <div>see Notification of Transmittal of International Search Report (Form PCT/ISA/220) as well as, where applicable, item 5 below.</div> </div> | |
| International application No. PCT/US00/16895 | International filing date (<i>day/month/year</i>) 19 JUNE 2000 | (Earliest) Priority Date (<i>day/month/year</i>) 17 JUNE 1999 |
| Applicant REGENTS OF THE UNIVERSITY OF CALIFORNIA | | |

This international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of 2 sheets.

☒ It is also accompanied by a copy of each prior art document cited in this report.

1. Basis of the report

a. With regard to the **language**, the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ the international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).

b. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international search was carried out on the basis of the sequence listing:

☐ contained in the international application in written form.

☐ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority in written form.

☐ furnished subsequently to this Authority in computer readable form.

☐ the statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

☐ the statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

2. ☐ **Certain claims were found unsearchable** (See Box I).

3. ☐ **Unity of invention is lacking** (See Box II).

4. With regard to the **title**,

☒ the text is approved as submitted by the applicant.

☐ the text has been established by this Authority to read as follows:

5. With regard to the **abstract**,

☒ the text is approved as submitted by the applicant.

☐ the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box III. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. The figure of the **drawings** to be published with the abstract is Figure No. _____

☐ as suggested by the applicant.

☐ because the applicant failed to suggest a figure.

☐ because this figure better characterizes the invention.

☒ None of the figures.

INTERNATIONAL SEARCH REPORT

International application No.

US00/16895

A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) : A01N 1/02

US CL : 435/1.1, 1.2

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 435/1.1, 1.2

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

Ca on line, USPATFULL, Medline, Biosis

C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category* | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|---------------|--|-----------------------|
| X --- Y | US 5,814,601 A (WINSLOW et al.) 29 September 1998, col. 11 and 12. | 2 --- 1,3 |
| Y | US 5,374,624 A (SEGEL) 20 December 1994, Table 1. | 1-3 |
| X | NAKAJIMA et al. Forty-eight hour liver preservation using an artificial blood substitute. Asaio Transactions. Jul-Sep 1988, Vol. 34, No. 3, pages 277-279, especially Table 1. | 2,3 |

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

| | |
|---|--|
| * Special categories of cited documents | *T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention |
| *A* document defining the general state of the art which is not considered to be of particular relevance | *X* document of particular relevance, the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone |
| *E* earlier document published on or after the international filing date | *Y* document of particular relevance, the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art |
| *L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) | *G* document member of the same patent family |
| *O* document referring to an oral disclosure, use, exhibition or other means | |
| *P* document published prior to the international filing date but later than the priority date claimed | |

Date of the actual completion of the international search

23 AUGUST 2000

Date of mailing of the international search report

20 SEP 2000

Name and mailing address of the ISA/US
Commissioner of Patents and Trademarks
Box PCT
Washington, D.C. 20231

Facsimile No. (703) 305-3230

Authorized officer

SANDRA SAUCIER

Telephone No. (703) 308-0196

We claim:

1 1. A composition for donor organ preservation for transplantation
2 comprising an ischemic hypothermic immersion saline solution including PEG-Hb,
3 human albumin, dextrose, heparin sodium, lidocaine HCl, MgSO₄, KCl, CaCl₂,
4 THAM, NaCl, NaHCO₃, and Na₃PO₄.

1 2. A composition for donor organ preservation for transplantation
2 comprising a polyethylene glycol coated bovine hemoglobin based solution for the
3 purpose of ex vivo donor organ preservation to preserve donor human and animal
4 organs, *ex vivo*, prior to transplantation.

1 3. A composition for donor organ preservation for transplantation
2 comprising an oxygen, nutritional and electrolyte environment to tissue of the
3 donor organ to provide *ex vivo* preservation such that the donor organ will regain
4 acceptable function post transplantation.